4/5/91

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

APR -5 1991

MEMORANDUM

SUBJECT: Garlon 3A Herbicide - Request for an Extension of the EUP (No. G2719-EUP-1) and Temporary tolerances for Triclopyr in Fish, and Shellfish (EPA Reg. No. 62719-37)

Tox Chem No.: 882I
HED Project No.: 1-0567

FROM: Yiannakis M. Ioannou, Ph.D Section Head
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3/29/91

TO: Robert Taylor, PM 25
Fungicide - Herbicide Branch
Registration Division (H7505C)

THRU: Marcia van Gemert, Ph.D., Branch Chief
Toxicology Branch II (HFAS)
Health Effects Division (H7509C)

Marcia van Gemert
4/3/91

Registrant: DowElanco, Indianapolis, Indiana

Action Requested: Determine if the existing toxicology data base on Triclopyr (Garlon 3A) will support extension of the Experimental Use Permit and temporary tolerances for Triclopyr in fish, shellfish and potable water.

Recommendations: The toxicology data base for Triclopyr (Garlon 3A) is not adequate at present to support the renewal of the EUP and temporary tolerances for fish, shellfish and potable water.

Considerations

Dow Chemical Company was granted an EUP and temporary tolerances for Trichopyr and it s metabolites for fresh water fish and shellfish at 0.2 ppm and potable water at 0.5 ppm (memo of W.S. Woodrow dated 5-15-86). With the present submission, DowElanco is requesting a 2-year extension of the EUP and its attendant temporary tolerances for fish, shellfish and potable water. Triclopyr (Garlon 3A) will be applied at the rate of 1/3 to 3 gallons per acre to control woody plants and annual and perennial weeds in streams, rivers, ponds, lakes, reservoirs, irrigation canals and other sites. A maximum of 48,960 lbs (16,320 gallons) of Garlon 3A will be applied on 2,040 acres in 22 states over the 2-year period.

Triclopyr is a List B chemical and its data base is currently being reevaluated under the FIFRA 88 authorization. Data requirements for Triclopyr technical and the end use product (Garlon 3A) to support the requested EUP and temporary tolerances are listed on the attached table. All studies required but not submitted and those studies classified as "Core-supplementary" are considered data gaps. At present, the acute inhalation, primary eye irritation, primary dermal irritation, dermal sensitization and the rat chronic toxicity study with Triclopyr technical are considered data gaps. Although the rat chronic toxicity study was evaluated by Toxicology Branch over three years ago (Memo of Y. M. Ioannou, dated 3-28-88; document #006683), the petitioner failed to address the deficiencies of this study with possibly upgrading the study from Core-supplementary to Core-minimum classification.

Conclusions

Based on the aforementioned considerations, Toxicology Branch II has determined that the available toxicology data base for Triclopyr is not adequate to support renewal of the EUP and temporary tolerances requested by the registrant.

Toxicology Profile for Triclopyr Technical and Garlon 3A

A. Data Requirements

Formulation (Garlon 3A; 44.4% ai)	Required	Submitted	Core-Classification
81-1 Acute Oral Toxicity	Y	Y	Not reviewed
81-2 Acute Dermal Toxicity	Y	Y	Not reviewed
81-3 Acute Inhalation Toxicity	Y	Y	Not reviewed
81-4 Primary Eye Irritation	Y	Y	Not reviewed
81-5 Primary Dermal Irritation	Y	Y	Not reviewed
81-6 Dermal Sensitization	Y	Y	Not reviewed
Triclopyr Technical			
81-1 Acute Oral Toxicity	Y	Y	Minimum
81-2 Acute Dermal Toxicity	Y	Y	Minimum
81-3 Acute Inhalation Toxicity	Y	N	-
81-4 Primary Eye Irritation	Y	Y	Supplementary
81-5 Primary Dermal Irritation	Y	Y	Supplementary
81-6 Dermal Sensitization	Y	N	-
81-1 Subchronic Oral (Rodent)	Y	Y	Minimum
82-1 Subchronic Oral (Nonrodent)	Y	Y	Supplementary[1]
83-1 Chronic Toxicity (Rodent)	Y	Y	Supplementary
83-1 Chronic Toxicity (Nonrodent)	Y	Y	Not reviewed
83-3 Developmental Toxicity (rat)	Y	Y	Minimum
83-3 Developmental Toxicity (rabbit)	Y	Y	Minimum
83-4 Reproduction (rat)	Y	Y	Minimum
84-2 Mutagenicity - Gene Mutation	Y	Y	Acceptable
84-2 Mutagenicity - Str. Chrom. Aber.	Y	Y	Acceptable
84-4 Mutagenicity - Other Genotoxic Effects	Y	Y	Acceptable

[1]This requirement can be satisfied by an acceptable 6-month dog feeding study.

B. Toxicology Issues

1. Reference Dose (RFD)

The current RFD for Triclopyr is set at 0.025 mg/kg/day based on a 6-month dog study with a NOEL of 2.5 mg/kg/day and a safety factor of 100. This RFD value has not been reviewed by the HED RFD committee and not verified by other Agency RFD committees due to major data gaps existing in the Triclopyr Toxicology data base.

2. Pending Regulatory Actions

The Toxicology Branch is not aware of any pending regulatory actions against this pesticide.